UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/522,727 | 03/10/2000 | Wayne A Marasco | 47577-C | 5205 |

40679 7590 02/07/2005

RONALD I. EISENSTEIN
NIXON PEABODY LLP
100 summer street
BOSTON, MA 02110

| EXAMINER | |
|---|---|
| OUSPENSKI, ILIA I | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1644 | |

DATE MAILED: 02/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/522,727 | MARASCO ET AL. | |
| | Examiner | Art Unit | |
| | ILIA OUSPENSKI | 1644 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *22 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,4 and 7-24* is/are pending in the application.

4a) Of the above claim(s) *1, 4, 7-17, 20-21, and 24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18, 19, 22, and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

1. The examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Ilia Ouspenski, Group Art Unit 1644, Technology Center 1600.

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/22/2004 has been entered.

3. Applicant's amendment, filed 11/22/2004, is acknowledged.

Claims 2, 3, and 5 have been cancelled.
Claim 6 has been cancelled previously.
Claims 1 and 4 have been amended.
Claims 18 – 24 have been added.
Claims 8 – 12, 14 – 15, and 17 have been withdrawn from consideration previously.

*Claims 1, 4, and 7 – 24 are pending.*

4. Amended claim 1, and claims dependent thereon, and newly added claims 20, 21, and 24 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Newly amended/submitted claims are directed to a method which differs with respect to one or more of ingredients and

method steps from the method previously claimed; therefore, the newly claimed method is patentably distinct.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 1, 4, 7, 13, 16, 20, 21, and 24 are withdrawn from consideration as being directed to a non-elected invention. See 37 C.F.R. § 1.142(b) and M.P.E.P. § 821.03.

Non-elected claims 8 – 12, 14 – 15, and 17 are held to be withdrawn from further consideration under 37 CFR 1.142(b) as acknowledged in the previous Office Action, mailed 11/20/2003.

*Consequently, claims 18, 19, 22, and 23, as they read on the originally presented invention, are under consideration in the instant application.*

5. This Office Action will be in response to applicant's arguments, filed 11/22/2004.

The rejections of record can be found in the previous Office Action.

The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

*(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.*

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 18, 19, 22, and 23 rejected under **35 U.S.C. 103(a)** as being unpatentable over Marasco et al. (WO 94/02610, of record, see entire document) in view of Marasco et al. (US Patent No. 6,143,520; see entire document).

The applied references have a common Inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

As discusses in previous Office Actions, WO 94/02610 teaches methods of intracellular binding of target molecules by expressing a gene encoding a single chain antibody in a cell (see entire document, e.g., Abstract and "Summary of the Invention" on pages 4-5). WO 94/02610 teaches that this method can be applied to disrupt a function that is undesirable at a particular time, including the recognition of antigens by the immune system at times when an immune response is undesired, as during transplantation of organs (see entire document, but especially e.g. page 16 lines 1-16). WO 94/02610 further teaches that said single chain antibody can be a Fab fragment (e.g. page 24 last paragraph, page 44 last paragraph, or claim 47), and that the preferred vector for expression of the antibody is a retroviral vector (e.g. pages 46 – 47 bridging paragraph). WO 94/02610 reviews a need for such methods at the time the invention was made (page 3 line 22 – page 4 line 5).

WO 94/02610 does not teach the use of an internal ribosome entry site (IRES) for expression of the antibody, and does not specifically exemplify the use of lentivirus vectors.

US Patent No. 6,143,520 teaches and claims lentivirus vectors containing IRES for expression of genes of interest (see entire document, in particular, e.g. claim 1), such as those encoding intracellular antibodies (intrabodies) (e.g. column 3 first paragraph). US Patent No. 6,143,520 further discloses numerous advantages of using IRES in general, an in combination with a lentivirus vector in particular, over other expression systems, and especially as it applies to expression of intrabodies (see entire document, in particular, e.g. Results at columns 8 – 9).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply the teaching of US Patent No. 6,143,520 to those of WO 94/02610 to arrive at the claimed method. One of ordinary skill in the art at the time the invention was made would have been motivated to do so, because of the need for such methods, as reviewed by WO 94/02610, and the advantages of using IRES and

lentivirus vectors for expression of intrabodies, as taught by US Patent No. 6,143,520. One of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention, as demonstrated by the Examples in US Patent No. 6,143,520.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

***8. Conclusion: No claim is allowed.***

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ILIA OUSPENSKI
Patent Examiner
Art Unit 1644

PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER
TECH CENTER 1600
2/3/05

February 1, 2005